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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,094

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Enrico Gerardus Albertus Linders

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SYNGENTA BIOTECHNOLOGY, INC.

PATENT DEPARTMENT

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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/522,094	<b>Applicant(s)</b> LINDERS ET AL.	
	<b>Examiner</b> KEITH O. ROBINSON	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 55-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 4, 2009 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicant's cancellation of claims 1-54 and addition of new claims 55-74, filed May 4, 2009, have been received and entered in full.

3. Claims 55-74 are under examination.

### ***Response to Arguments***

4. Applicant's cancellation of claims 1-54 has rendered the 35 USC 112, second paragraph rejection on page 2 of the Office Action mailed February 3, 2009 moot. See page 4, 2<sup>nd</sup> paragraph of 'Remarks' filed May 4, 2009.

5. Applicant's cancellation of claims 1-54 has rendered the 35 USC 112, first paragraph rejection for written description on pages 2-6 of the Office Action mailed February 3, 2009 moot. See page 4, 5<sup>th</sup> paragraph of 'Remarks' filed May 4, 2009. Applicant's arguments regarding the 35 USC 112, first paragraph written description rejection are addressed below for the pending claims.

6. Applicant's cancellation of claims 1-54 has rendered the 35 USC 112, first paragraph rejection for enablement on pages 6-9 of the Office Action mailed February 3, 2009 moot. See page 6, last paragraph of 'Remarks' filed May 4, 2009. Applicant's arguments regarding the 35 USC 112, first paragraph enablement rejection are addressed below for the pending claims.

7. Applicant's cancellation of claims 1-54 has rendered the 35 USC 103 rejection on pages 10-12 of the Office Action mailed February 3, 2009 moot. It is noted that Applicant has not provided any arguments for the 35 USC 103 rejection on pages 10-12 of the Office Action mailed February 3, 2009.

***Claim Rejections - 35 USC § 112, first paragraph – Written Description***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 55-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any *B. oleracea* plant resistant to clubroot disease, wherein the resistance is obtained from a clubroot resistant *B. rapa* plant,

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wherein the clubroot resistant *B. rapa* plant is a Chinese cabbage F1 hybrid 'Parkin' and the resistance to clubroot is monogenic and dominant.

See MPEP 2163(I) where it states "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116".

The specification only provides evidence that Applicant was only in possession of *B. oleracea* line CFL667, wherein said line was derived from an interspecific cross of clubroot resistant Chinese cabbage F1 hybrid from Japan commercially available under the name 'Parkin' and an disclosed broccoli plant (see, for example, pages 10-11).

MPEP 2163(I) also states, "[a]n application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801 et seq. See *Enzo Biochem*, 323 F.3d at 965, 63 USPQ2d at 1614 ("reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material").

MPEP 2163.02 states, "[u]nder *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art

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that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed”.

In the instant case, Applicant has conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicant was in possession of *B. oleracea* line CFL667 (see page 11 of the specification).

Thus, based on the disclosure of the specification, Applicant has only shown possession of *B. oleracea* line CFL667.

See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

Applicant has possession of a narrow genetic base and is broadly claiming the phenotype. Applicant is in possession of a narrow invention limited to a particular deposited line; however, they are broadly claiming every *B. oleracea* plant that has the phenotype of their plant. This is paramount to selecting a seed line for high yield and then claiming every seed line that has high yield, regardless of how they are made. It would be like selecting a seed line for its color and then claiming every seed that happens to have that characteristic regardless of how it was derived.

Applicant argues that the specification provides evidence that Applicant was in possession of multiple variants and cites pages 11 and 12 of the specification where it states, "the resistance to clubroot was transferred to other *B. oleraceas*, in particular white cabbage, cauliflower and Brussels sprouts, using standard breeding techniques well-known in the Brassica art. The trait was also further introgressed into *B. oleracea* elite lines". See page 4, last paragraph to page 6, lines 1-2 of 'Remarks' filed May 4, 2009.

This is not persuasive. Though the specification provides evidence of broccoli, white cabbage, cauliflower and Brussels sprouts having resistance to clubroot disease, the specification fails to provide any evidence of Borecole, Savoy and red cabbage having resistance to clubroot disease as is claimed in claim 58.

***Claim Rejections - 35 USC § 112, first paragraph – Enablement***

10. Claims 55-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the plant is essential to the claimed inventions, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a

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repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of seed of each of the claimed embodiments is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807) and,



(e) the deposit will be replaced if it should ever become inviable.

The specification fails to provide any deposit information detailing the conditions under which Chinese cabbage F1 hybrid 'Parkin' was deposited.

It is noted that on page 11 of the specification *B. oleracea* line CFL667 was deposited with NCIMB under accession NCIMB 41134; however, the specification fails to provide any deposit information detailing the conditions under which *B. oleracea* line CFL667 was deposited. The deposit of the seed should comply 37 CFR 1.801-1.809 as indicated above.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 55-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiang et al (Euphytica 32: 479-483, 1983), in view of Ludwig-Muller (Phytochemistry 44(3): 407-414, 1997), in view of Kuginuki et al (European Journal of Plant Pathology 105: 327-332, 1999), in view of Landry et al (Genome 35(3): 409-420, 1992).

The claims read on a *B. oleracea* plant resistant to clubroot disease, wherein the resistance is obtained from a clubroot resistant *B. rapa* plant, wherein the clubroot resistant *B. rapa* plant is a Chinese cabbage F1 hybrid 'Parkin' and the resistance to clubroot is monogenic and dominant.

With regard to claims 55 and 68-70, Chiang et al teach a *B. oleracea* plant resistant to clubroot disease, wherein the resistance is obtained from a clubroot resistant *B. napus* plant and the resistance to clubroot is monogenic and dominant. See, for example, page 482, 1st paragraph where it states, "the inheritance of resistance to...the clubroot pathogen is controlled by a single dominant gene...[and] the monogenic dominant inheritance found in this study indicates that this single gene is located on a chromosome in the 'a1' genome".

Chiang et al do not teach a clubroot resistant *B. rapa* plant, wherein the clubroot resistant *B. rapa* plant is Chinese cabbage F1 hybrid 'Parkin'.

Ludwig-Muller et al teach a clubroot resistant *B. rapa* plant, wherein the clubroot resistant *B. rapa* plant is Chinese cabbage 'Parkin'. See, for example, page 409, Table 1 where it teaches that 'Parkin' had 0% infection with *Plasmodiophora* (i.e., clubroot disease).

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With regard to claims 56 and 57, Kuginuki et al teach rating Brassica plants for clubroot resistance. See, for example, page 328, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph where it teaches that plants were rated on a scale from 0 to 3, wherein 0 indicated a plant that was resistant to clubroot. It would have been obvious to one of ordinary skill in the art that rating systems can vary.

With regard to claim 58, Chiang et al teach a *B. oleracea* plant that is a cabbage. See, for example, page 480, Figure 1. See also page 410, 1<sup>st</sup> column, last paragraph of Landry et al where it teaches cabbage.

With regard to claims 59, 61 and 62, Landry et al teach resistance linked to a molecular marker. See, for example, page 417, 1<sup>st</sup> column, last paragraph to 2<sup>nd</sup> column, lines 3-4, where it teaches that two markers are associated with linkage group 1 (monogenic) and that alleles of line 86-16-5 are dominant for resistance to clubroot.

With regard to claims 63 and 64, Chiang et al teach that the inheritance to clubroot resistance is controlled by a single dominant gene; see, for example, page 482, 1<sup>st</sup> paragraph; therefore it would be obvious to one of ordinary skill in the art that a *B. oleracea* plant that is homozygous or heterozygous for resistance would each display resistance to clubroot.

With regard to claims 65 and 66, Landry et al teach inbred and hybrid *B. oleracea* plants. See, for example, page 416, Figure 5 where it teaches inbred lines and hybrid plants produced by crossing said inbred lines.

With regard to claim 67, Chiang et al teach cytoplasmic male sterile Brassica plants. See, for example, page 480, Figure 1.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the above teachings to produce a *B. oleracea* plant resistant to clubroot disease, wherein the resistance is obtained from a clubroot resistant *B. rapa* plant, wherein the clubroot resistant *B. rapa* plant is a Chinese cabbage F1 hybrid 'Parkin' and the resistance to clubroot is monogenic and dominant.

One of ordinary skill in the art would have been motivated to combine these teachings because Chiang et al teach that the successful transfer of a single dominant gene responsible for resistance to clubroot from *B. napus* to *B. oleracea* should be extremely useful in producing commercial F1 hybrids in cole crops (see page 482, last paragraph) and Ludwig-Muller et al teach that "the variety 'Parkin' showed no clubroot symptoms (see page 407, Abstract).

In addition, one of ordinary skill in the art would have reasonable expectation of success based on the success of Chiang et al in producing a *B. oleracea* plant resistant to clubroot disease wherein the resistance was obtained from a *B. napus* plant.

In *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007), the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art." It states "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at \_\_\_, 82 USPQ2d at 1395. The Supreme Court further stated that:

"When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a

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person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Id.* at \_\_\_\_, 82 USPQ2d at 1396.

See also *United States v. Adams*, . . . [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *Id.* at \_\_\_\_, 82 USPQ2d at 1395”; *Ex parte Kubin*, 83 USPQ2d 1410 (*Bd. Pat. App. & Int.* 2007); and *Ex parte Smith*...USPQ2d-at 20 (*Bd. Pat. App & Interf.* June 25, 2007) (citing *KRS*, 82 USPQ2d at 1396) (available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

### ***Conclusion***

14. Claims 71-74 appear to be free of the prior art given the failure of the prior art to teach or suggest *B. oleracea* plant line CFL667.

15. No claims are allowed.

### ***Contact Information***

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH O. ROBINSON whose telephone number is (571)272-2918. The examiner can normally be reached Monday – Friday, 8:00 a.m. - 4:30 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson  
/David H Kruse/  
Primary Examiner, Art Unit 1638